

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**DEVICOR MEDICAL PRODUCTS, INC.** )

300 E-Business Way )

Sharonville, Ohio 45241 )

Plaintiff, )

v. )

C.A. No. \_\_\_\_\_

**FOCAL THERAPEUTICS, INC.** )

4370 Alpine Rd. #101 )

Portola Valley, CA 94028 )

Defendant. )

DEMAND FOR JURY TRIAL

**COMPLAINT**

Plaintiff Devicor<sup>®</sup> Medical Products, Inc. (“Devicor”) brings this action against Focal Therapeutics, Inc. (“Focal”) and alleges as follows:

**PARTIES**

1. Devicor is a corporation registered in Delaware with its principal place of business at 300 E-Business Way, Sharonville, Ohio 45241.
2. On information and belief, Focal is a corporation organized under the laws of Delaware with its principal place of business at 4370 Alpine Road, Suite 101, Portola Valley, CA 94028.

**JURISDICTION AND VENUE**

3. This action is for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and seeks damages and injunctive relief. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. Upon information and belief, this Court has personal jurisdiction over Focal because, *inter alia*, it is incorporated in Delaware and purposefully avails itself of the rights and benefits of Delaware law.

5. Venue is proper pursuant to 28 U.S.C. § 1391(b) and § 1400(b). On information and belief, Focal has transacted business in this District, and has committed and/or induced acts of patent infringement in this District.

### **BACKGROUND**

6. Devicor is a global medical products company dedicated to the investment in, and development of, technologies that facilitate minimally invasive medical procedures. Among the medical products that Devicor develops and markets are tissue marking devices for use in breast procedures.

7. Typically, when a patient undergoes a breast procedure such as a biopsy or lumpectomy, tissue is removed. For any given procedure, a subsequent examination or treatment of the site is often needed. Thus, there is an important need to be able to relocate the site from which tissue is taken. Inserting a tissue marker at the site is one way to relocate the site at a subsequent examination.

8. Devicor offers a family of tissue marker products for breast biopsy procedures, visible under various imaging modalities, such as to radiographically mark a biopsy site.

9. Upon information and belief, Focal offers for sale, sells, and has sold tissue markers for breast procedures in this District and throughout the United States. For example, Focal's BioZorb™ line of products includes the BioZorb™ tissue marker for use in the breast. Upon information and belief, a reasonable opportunity for discovery will show that at least the BioZorb™ tissue markers infringe one or more claims of Devicor's asserted patents.

**PATENTS IN SUIT**

10. On August 7, 2001, the United States Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 6,270,464 (“the ’464 patent”), entitled “Biopsy Localization Method and Device.” The ’464 patent’s inventors are Richard E. Fulton, III and William R. Dubrul. Devicor is the owner of all right, title, and interest in the ’464 patent. A true and correct copy of the ’464 patent is attached hereto as Exhibit 1.

11. On March 12, 2002, the USPTO issued U.S. Patent No. 6,356,782 (“the ’782 patent”), entitled “Subcutaneous Cavity Marking Device and Method.” The ’782 patent’s inventors are D. Laksen Sirimanne, Douglas S. Sutton, Natalie V. Fawzi, and Gail Lebovic. Devicor is the owner of all right, title, and interest in the ’782 patent. A true and correct copy of the ’782 patent is attached hereto as Exhibit 2.

12. On November 27, 2012, the USPTO issued U.S. Patent No. 8,320,993 (“the ’993 patent”), entitled “Subcutaneous Cavity Marking Device.” The ’993 patent’s inventors are D. Laksen Sirimanne, Douglas S. Sutton, Natalie V. Fawzi, and Gail Lebovic. Devicor is the owner of all right, title, and interest in the ’993 patent. A true and correct copy of the ’993 patent is attached hereto as Exhibit 3.

13. On December 3, 2013, the USPTO issued U.S. Patent No. 8,600,481 (“the ’481 patent”), entitled “Subcutaneous Cavity Marking Device.” The ’481 patent’s inventors are D. Laksen Sirimanne, Douglas S. Sutton, Natalie V. Fawzi, and Gail Lebovic. Devicor is the owner of all right, title, and interest in the ’481 patent. A true and correct copy of the ’481 patent is attached hereto as Exhibit 4.

**FIRST CAUSE OF ACTION**  
**INFRINGEMENT OF U.S. PATENT NO. 6,270,464**

14. Devicor realleges and incorporates by reference the allegations of paragraphs 1-13 herein.

15. On information and belief, Focal has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, one or more claims of the '464 patent by making, having made, using, importing, selling, and/or offering for sale in the United States one or more tissue markers that embody the invention claimed in the '464 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the BioZorb™ line of products.

16. Focal has specifically induced and continues to induce others to infringe the '464 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Focal to be acts of infringement of the '464 patent with intent that those performing the acts infringe the '464 patent. Focal, upon information and belief, *inter alia*, advertises regarding the BioZorb™ line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

17. Focal also contributes to infringement of the '464 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or importing components, including the BioZorb™ line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '464 patent. These products are known by Focal to be especially made or especially adapted for use in

infringement of the '464 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

18. By infringing the '464 patent, Focal has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

19. By way of its past and continued acts of infringement of Devicor's patents, Focal has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's patents.

20. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Focal is enjoined from infringing Devicor's '464 patent.

21. Upon information and belief, Focal's infringement of the '464 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys' fees pursuant to 35 U.S.C. § 285.

**SECOND CAUSE OF ACTION**  
**INFRINGEMENT OF U.S. PATENT NO. 6,356,782**

22. Devicor realleges and incorporates by reference the allegations of paragraphs 1-21 herein.

23. On information and belief, Focal has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, one or more claims of the '782 patent by making, having made, using, importing, selling, and/or offering for sale in the United States one or more tissue markers that embody the invention claimed in the '782 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the BioZorb™ line of products.

24. Focal has specifically induced and continues to induce others to infringe the '782 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Focal to be acts of infringement of the '782 patent with intent that those performing the acts infringe the '782 patent. Focal, upon information and belief, *inter alia*, advertises regarding the BioZorb™ line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

25. Focal also contributes to infringement of the '782 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or importing components, including the BioZorb™ line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '782 patent. These products are known by Focal to be especially made or especially adapted for use in infringement of the '782 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

26. By infringing the '782 patent, Focal has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

27. By way of its past and continued acts of infringement of Devicor's patents, Focal has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's '782 patent.

28. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Focal is enjoined from infringing Devicor's patents.

29. Upon information and belief, Focal's infringement of the '782 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys' fees pursuant to 35 U.S.C. § 285.

**THIRD CAUSE OF ACTION**  
**INFRINGEMENT OF U.S. PATENT NO. 8,320,993**

30. Devicor realleges and incorporates by reference the allegations of paragraphs 1-29 herein.

31. On information and belief, Focal has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, one or more claims of the '993 patent by making, having made, using, importing, selling, and/or offering for sale in the United States one or more tissue markers that embody the invention claimed in the '993 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the BioZorb™ line of products.

32. Focal has specifically induced and continues to induce others to infringe the '993 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Focal to be acts of infringement of the '993 patent with intent that those performing the acts infringe the '993 patent. Focal Therapeutics, upon information and belief, *inter alia*, advertises regarding the BioZorb™ line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

33. Focal also contributes to infringement of the '993 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or

importing components, including the BioZorb™ line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '993 patent. These products are known by Focal to be especially made or especially adapted for use in infringement of the '993 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

34. By infringing the '993 patent, Focal has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

35. By way of its past and continued acts of infringement of Devicor's patents, Focal has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's '993 patent.

36. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Focal is enjoined from infringing Devicor's patents.

37. Upon information and belief, Focal Therapeutics' infringement of the '993 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys' fees pursuant to 35 U.S.C. § 285.

**FOURTH CAUSE OF ACTION**  
**INFRINGEMENT OF U.S. PATENT NO. 8,600,481**

38. Devicor realleges and incorporates by reference the allegations of paragraphs 1-37 herein. 8,600,481

39. On information and belief, Focal has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, one or more claims of the '481 patent, which is not under reexamination, by making, having made, using, importing, selling, and/or offering for sale in the United States one or more tissue markers that embody the



invention claimed in the '481 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the BioZorb™ line of products.

40. Focal has specifically induced and continues to induce others to infringe the '481 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Focal to be acts of infringement of the '481 patent with intent that those performing the acts infringe the '481 patent. Focal Therapeutics, upon information and belief, *inter alia*, advertises regarding the BioZorb™ line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

41. Focal also contributes to infringement of the '481 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or importing components, including the BioZorb™ line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '481 patent. These products are known by Focal to be especially made or especially adapted for use in infringement of the '481 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

42. By infringing the '481 patent, Focal has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

43. By way of its past and continued acts of infringement of Devicor's patents, Focal has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's '481 patent.

44. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Focal is enjoined from infringing Devicor's patents.

45. Upon information and belief, Focal Therapeutics' infringement of the '481 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys' fees pursuant to 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Devicor prays that this Court:

A. Enter judgment in favor of Devicor that Focal directly and/or indirectly infringes claims of each of the four Devicor patents identified above;

B. Enter judgment enjoining Focal from selling, offering to sell, making, using, or importing any product that infringes any claim of any of the four Devicor patents identified above;

C. Award Devicor damages pursuant to 35 U.S.C. § 284, including costs and pre- and post-judgment interest;

D. Award Devicor treble damages under 35 U.S.C. § 284 as a result of Focal Therapeutics' willful infringement of Devicor's patents;

E. Declare this case exceptional under 35 U.S.C. § 285 and award Devicor reasonable attorneys' fees, costs, and expenses; and

F. Award Devicor such other relief as the Court deems just and appropriate.

**DEMAND FOR JURY TRIAL**

Devicor demands a trial by jury on all issues so triable.

DATED: June 4, 2014

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*/s/ Karen L. Pascale*

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